

CASE NO. A06-0710

State of Minnesota
In Court Of Appeals

Svenn Borgersen,
Appellant,

vs.

Cardiovascular Systems, Inc.
Respondent.

APPELLANT'S BRIEF AND APPENDIX

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STATEMENT OF ISSUES

1. Did the District Court err as a matter of law in considering extrinsic evidence in the interpretation of an express employment contract when the contract was not ambiguous and contained an integration clause?

Resolution Below:

The Court looked outside of the contract to determine the intent of the parties.

Apposite Authorities:

Alpha Real Estate v. Delta Dental Plan, Minn., 664 N.W. 2d 303 (Minn. 2003)

Kvidera v. Rotation Engineering and Mfg. Co., 705 N.W. 2d 416 (Minn. App. 2005)

Apple Valley Red-E-Mix v. Mills-Winfield, 436 N.W. 2d 121 (Minn. App. 1989)

ICC Leasing Corp. v. Midwestern Mach. Co., 257 N.W. 2d 551 (Minn. 1977)

2. If the District Court did not err in considering extrinsic evidence, was the intent of the parties to the employment contract a genuine issue of material fact in dispute that precluded summary judgment?

Resolution Below:

The Court determined that the issue of whether the parties intended the employment relationship to be at-will or terminable for cause did not involve disputed facts.

Apposite Authorities:

Denelsbeck v. Wells Fargo & Co., 666 N.W. 2d 339 (Minn. 2003)

Hillgoss v. Cargill, Inc., 649 N.W. 2d 142 (Minn. 2002)

3. Did the District Court err in determining that Appellant did not make a report protected by Minn. Stat. § 181.932?

Resolution Below:

The Court determined that Appellant did not make a protected report.

Apposite Authorities:

Minn. Stat. § 181.932

21 C.F.R. § 812.20

21 C.F.R. § 812.25

21 C.F.R. § 812.36(c)(1)(vii)

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I.

STATEMENT OF THE CASE

Appellant has appealed from a summary judgment dismissing his lawsuit. Summary judgment was granted by District Court Judge Marilyn Justman Kaman of the Hennepin County District Court and judgment was entered on February 27, 2006. This appeal from the judgment was filed on April 10, 2006.

Appellant sued Cardiovascular Systems, Inc. ("CSI") for breach of an express employment contract and unlawful termination under Minnesota's whistleblower law, Minn. Stat. § 181.932. Appellant was the Director of Design and Analysis at CSI. CSI was engaged in the research and development of a medical device to be used by cardiologists to remove tissue blocking the flow of blood in stents implanted in arteries and veins. CSI had submitted an application to the U.S. Food and Drug Administration (FDA) for permission to use the device in human clinical trials. The FDA responded by requiring additional testing of the device. CSI conducted the additional testing, which resulted in significant and potentially deadly failures of the device. Appellant reported to CSI that it must disclose the test results to the FDA in accordance with FDA regulations that required disclosure of all known risks associated with the device. CSI instead hid the test results from the FDA and terminated Appellant's employment.

Appellant had a written employment contract that required cause before his employment could be terminated. CSI had no cause under the contract. Appellant's efforts to get CSI to comply with FDA regulations were protected by Minn. Stat. § 181.932.

The District Court granted Respondent's motion for summary judgment. Appellant's cross motion to amend to his complaint to state a claim for punitive damages was held moot.

II.

STATEMENT OF FACTS

Plaintiff Svenn Borgersen has a Ph.D. in civil engineering from the University of Minnesota and has worked, among other places, at Honeywell, Medtronic and Boston Scientific. He also maintains his own consulting firm.

The Business of Cardiovascular Systems, Inc.

CSI is in the business of the research, design, development and eventual sale of a product known as the orbital atherectomy device (hereinafter "OAD"). The OAD is a gas powered, mechanical device designed to be used by cardiologists to remove tissue blocking the flow of blood in arteries and veins. It consists basically of a diamond-coated crown on a shaft that rotates at between 150,000 -- 200,000 rpms and cuts away these blockages. (Borgersen depo. 145-46). The OAD was specifically being engineered to remove blockages from stents in human arteries and in peripheral arteries and veins.¹

¹A more in depth explanation of the device is contained in Kallok depo. exh. 26 (taken from the company's original submission of the device for approval to the FDA).

The Hiring of Dr. Borgersen

On or about December 2, 2002, the company hired Dr. Michael Kallok as its Chief Executive Officer. Dr. Kallok then hired Dr. Borgersen, also in December of 2002. (Kallok depo., 22). Both Kallok and Borgersen had worked together at Boston Scientific. (Kallok depo., 17-18)(Borgersen depo., 55-56).

The Employment Agreement of Dr. Borgersen

Dr. Borgersen was presented with an employment agreement by Dr. Kallok, which the two of them signed (hereinafter the "Agreement"). The Agreement states:

"2. Term of Employment. The term of this Agreement shall commence on a mutually agreed-to date, but no later than January 13, 2003 and continue until terminated by either party as provided for hereunder."

"7. Termination of Employment.

"7.1 With Cause. Notwithstanding anything contained herein to the contrary, the Corporation, acting by and through its Board of Directors, shall have the right to immediately terminate Employee's employment under this Agreement for 'Cause,' which shall mean: (i) the willful and continued failure by the Employee to substantially perform Employee's duties with the Corporation; or (ii) the willful engaging by Employee in conduct which is demonstrably and materially in the opinion of the Board injurious to the corporation, monetarily or otherwise.

(App. 36-37). Paragraph 7 goes on to allow for termination in the event of death, disability or dissolution of the corporation. The Agreement states no other terms under which it can be terminated.²

²The Agreement was in the name of "Shturman Cardiovascular Systems, Inc." which later changed its name to "Cardiovascular Systems, Inc." (Kallok depo. 20).

The Integration Clause.

The Agreement contains an integration clause that reads as follows:

“11.1 Integration. This agreement embodies the entire agreement and understanding among the parties relative to subject matter hereof and supersedes all prior agreements and understandings relating to such subject matter.”

(App. 40)

The Cover Letter

Accompanying the Agreement was a cover letter from Dr. Kallok stating “[t]his letter and the enclosed Employment Agreement summarize our understanding of the terms of your employment and provide you with the means to accept our offer as described. Upon acceptance of this offer and your active start of employment, you will become an ‘at will’ employee of Shturman Cardiovascular Systems, Inc. This means that you will be free to resign at any time. Likewise, Shturman Cardiovascular Systems will have the right to terminate your employment at any time with or without reason or notice. Acceptance of this offer acknowledges your understanding and acceptance of the ‘at will’ nature of your employment.” (App. 34).

Dr. Borgersen testified that the cover letter meant nothing to him. (Borgersen depo. 125-26). He testified that he and Kallok had a specific discussion concerning paragraph 7’s requirement of cause for termination. (Borgersen depo., 132). He never acknowledged the cover letter.

Kallok testified that the Agreement was drafted by CSI. (Kallok depo. 97-98). He further testified that he had read the Agreement through before presenting it to Dr. Borgersen, that his signature on the Agreement meant that he agreed with its terms, and that it was his decision to give the Agreement to Dr. Borgersen. Id.

No Cause Under the Agreement to Terminate

As the District Court noted, the termination would likely not meet the cause requirement of the Agreement. (Findings of Fact 27 and 28, Conclusion of Law 11). Dr. Kallok testified that the reason for terminating Dr. Borgersen was that “he simply was either incapable or unwilling to do the responsibilities of the job that we hired him to do.” (Kallok depo. 102-03). (Note that Dr. Borgersen disputes performance issues, but the dispute is unnecessary for the Court to resolve on appeal.) None of the three individuals who participated in the termination decision could offer testimony that would meet the “willful” aspect of the cause requirement of paragraph 7 of the Agreement. (Kallok depo. 104-05); (Flaherty depo. 39); (Shapland depo. 77). Furthermore, the company offered him a severance package with a consulting contract. (Kallok depo. exh. 37). It also circulated a memorandum to all employees stating how sorry they were to see him go and thanking him for his accomplishments. (App. 42). The consulting contract contained a release. (Kallok depo., 108).

There was No Vote of The Board of Directors on the Termination.

Contrary to the requirements of the Agreement, the board of directors of CSI never approved the termination of Dr. Borgersen's employment. (Flaherty depo. 43-44); (Kallok depo. 99-102).

The FDA Approval Process

A company seeking to bring a new medical device to the marketplace needs FDA approval. One of the steps in the process is to seek what is known as an Investigational Device Exemption ("IDE"). The IDE allows the company to test the device in human clinical trials. The application process for an IDE is governed by federal regulation. *See* 21 C.F.R. Part 812.

The Company's Application for an IDE

On October 20, 2003, in a "pre-IDE meeting", the FDA requested that CSI conduct certain tests of the device. It "recommended that bench testing include an evaluation of the possible interaction between the OAD and stents *under worst-case conditions*. This testing was to demonstrate that there is no possibility of interaction between the OAD and stents, or that the worst-case interactions do not adversely affect the stents (i.e. fatigue life, stent structure, etc.)". (App. 43)(emphasis added).

On February 12, 2004, the company submitted its application for an IDE for the use of the OAD in human clinical trials. (Warner aff. exh. D, cover letter of February 12, 2004,

to the FDA, doc. nos. CSI 01465-- 01467). It included animal testing on stent interaction, not the worst-case scenario bench testing that the FDA had previously requested. (App. 43).

On March 18, 2004, CSI received a lengthy reply from the FDA to its application. (App. 43). In its formal disapproval letter, the FDA listed a series of follow up issues it wanted CSI to address. (Kallok depo. 70-71). The FDA noted the absence of the stent interaction bench testing it had earlier twice requested and again asked CSI to provide it. (App. 43).

The minutes of an April 1, 2004, followup conference call between CSI officials and the FDA reflect that the FDA *for a third time* told CSI that “the FDA is requiring some additional bench testing to supplement that already completed to address the question of stent-OAD interaction . . . The FDA indicated concerns include *modifying the stent integrity*, embolization and *cutting a strut that remains in the blood path.*” (App. 50)(emphasis added)³

The Failed Stent-OAD Interaction Tests.

The follow-up stent-OAD interaction tests were conducted by a testing engineer, Alexsey Fillipov. (Vanden Hoek depo. 44-45). The bench testing that responded to the FDA’s request ended with catastrophic failures of the device. The device became entangled in the struts of the stent and caused the cutting surface of the device to slice through the simulated artery wall. (See App. 45, photograph of test results,)(Vanden Hoek depo. 49-52). Had this occurred in a human being, it could have been fatal. (Vanden Hoek depo. 46).

³As noted in the list of attendees, Dr. Borgersen was not on this conference call. Id. Working with the FDA was not his responsibility.

CSI contends, however, that these were not bench tests at all, but were simply tests to create a test. (See Findings of Fact 16). *Borgersen testified to the contrary.* (App. 51)(“[T]hey had a number of catastrophic failures during the testing process using test procedures that were perfectly representative of what was going on with the device to be used in the human body.”) The fact that the results were photographed is further evidence that it was a valid test. The District Court, despite noting the conflicting testimony, made a specific finding that agreed with CSI. (Finding of Fact 15-16; Conclusion of Law 26).

Dr. Kallok admitted going through 15-20 test variations before coming up with the test protocol that CSI submitted to the FDA. (Kallok depo. 77). Although Dr. Borgersen has his signature on the document finally submitted to the FDA, the final test protocol and test results that were attached to the signature page *were not what he had signed off on.* They were modified by others after his signature to fit the favorable test results. (App. 51). Dr. Borgersen also testified that certain measurements of damage to the stent struts contained in the report to the FDA were numbers that *he had never even seen before* and were not the numbers on the document that he had signed. (App. 51-52). Significantly, Borgersen was not asked to review what was actually submitted to the FDA. (App. 53).

CSI did not include results of the failed tests in its response to the FDA. (See Kallok depo. exh. 32, TD 04-417 OAD Stent Interaction Test Protocol and Report Bench Evaluation of Stent and OAD Interaction -- provided with Wyatt-Brown aff.)(Kallok depo. 70-76).

Instead, CSI misrepresented its knowledge to the FDA, stating that “[s]tent integrity evaluation from animal testing and bench evaluations *indicate minor to no stent and OAD interaction*. . . The results *indicate no stent structural failure* that would result in compromised vessel patency.” (App. 44)(emphasis added). CSI then recommended no additional testing be done on the device, despite knowing of the catastrophic failures. Id.

The test results CSI submitted were tests that had not done what the FDA had asked it to do. The FDA had specifically requested that the tests be conducted under worst case conditions, including situations involving “*not completely deployed stents*” (App. 43) and “*cutting a strut that remains in the blood path*” (App. 50)emphasis added). CSI now admits that it did not submit any test results to the FDA on stents that were not completely deployed. (Vanden Hoek depo. 44-45).

Dr. Kallok admitted that he knew that there are times when stents would not fully deploy in an artery. (Kallok depo. 77-80). Proper testing on not fully deployed stents was essential to the safety of those who would be the subjects of the human clinical trials. CSI had these test results, but hid them from the FDA.

Dr. Borgersen's Report to His Employer

When Dr. Borgersen was shown the results of the stent entanglement test by Mr. Phillipov, he took the matter straight to his superior Dr. Shapland. (App. 51)(“When Alexi (sic) showed me the results, I walked him directly across the hall to Ed Shapland's office and I said, ‘Come and take a look at this, you are not going to believe it.’ And when he came in

and looked at it I said, ‘Do you know what would happen if this was shown to the FDA? This could kill a patient . . .’

Dr. Borgersen also took the test results directly to Dr. Kallok. He told Dr. Kallok his “objection to use of the device in the human body was that[,] based on the tests[,] it was not safe to use them to remove stenosed tissue from stents.” (App. 53). He warned Dr. Kallok that the FDA should not approve the device for the proposed use in human clinical trials. Id.

“I was telling CSI that this kind of information needed to go to the FDA and should be part of our reporting procedure specifically if we were going to intend to clean out stents. This particular test finally convinced me that the device could not be safely used for that application.”

(App. 54).

Dr. Borgersen was not included in the final decision on what to include or not include in CSI’s response to the questions from the FDA. (App. 53). It was not his job responsibility to determine what went into an FDA submission or whether the company should seek FDA approval of a device. (App. 19; Finding of Fact 23).

On May 14, 2004, CSI submitted its response to the FDA’s disapproval letter, specifically omitting any mention of the failed test results. (See App. 43)(Kallok depo., 70-76). CSI included in its submission a signature page containing Dr. Borgersen’s signature, but what followed his signature was not at all what he had signed off on. (App. 52-53).

The Termination of Dr. Borgersen

Dr. Borgersen testified that his protected reports to Kallok and Shapland would have been made sometime between April 28, 2004, and May 14, 2004. (App. 51-52). On or about May 24, 2004, somewhere between ten to twenty-one days after his reports, Dr. Borgersen was fired. The exact date of the termination is uncertain, but on May 24, 2004, a notice was sent to employees announcing his separation from the company. (App. 42).

The FDA's Response to CSI's May 14, 2004, Submission

The FDA again disapproved CSI's application. It sent a disapproval letter on June 16, 2004. In the letter, the FDA criticized the supposed bench testing of stent interaction submitted by CSI, and concluded by again asking that CSI "provide bench testing information which adequately characterizes the potential for OAD and stent interaction *under worst-case conditions.*" (Warner aff. exh. F, at CSI 02853)(emphasis added). The FDA reiterated its numerous requests for this type of testing and the failure of CSI to do what it had asked it to do. CSI, of course, had already conducted these tests -- it had just not told the FDA the results.

Dr. Borgersen's Post-Termination Memo to CSI and the FDA

On June 16, 2004, a few weeks after his termination, Dr. Borgersen wrote to Kallok and Shapland reiterating what he had told them about the safety of the OAD, concluding "that the current design of the . . . OAD, as has been submitted to the [FDA] for Investigational Device Exemption (IDE), poses a very real potential threat to human life,

should not be allowed to proceed to human clinical trials, and the IDE submittal should be withdrawn immediately until these concerns are rectified.” (Borgersen depo., exh. 22).

In a Board meeting of June 21, 2004, *five days after the second disapproval letter* by the FDA and Dr. Borgersen’s own letter to CSI, the company dropped its pursuit of the instant application for the OAD. (Flaherty aff. exh. B). The company knew its device could not survive the worst-case testing the FDA kept insisting on.⁴

Unaware of the FDA’s disapproval letter, Dr. Borgersen sent an e-mail on July 22, 2004, to the FDA outlining in detail his concerns that CSI was pushing to have a potentially dangerous device approved by the FDA. (Borgersen depo., 203-04).⁵

The Company Tabled its Efforts for an IDE for use of the Device in Stents

The FDA conducted an on-site inspection in September of 2004 in response to the complaint from Dr. Borgersen. The FDA faulted CSI for having “no documentation covering the [test system development] that resulted in entanglement, or the 15-20 test system models to simulate a stenosed stent-in-artery before the model used in the 5/11/04 testing reported”. The report also found that “[n]o investigation or documentation of the

⁴The turnaround by CSI after the June 16, 2004, disapproval letter from the FDA was dramatic. In minutes of a Board meeting only a month earlier, the company noted that it “[e]xpected IDE approval June 2004”, outlined the number of patients it expected to use the device on in human clinical trials and stated when it expected to obtain final FDA approval for the device for use in the general public. (Warner aff. exh. G, CSI 02942).

⁵Dr. Borgersen is not claiming that his after termination reports are protected by the whistleblower law.

initial entanglement was performed until 8/04 and *it was not reported to FDA though FDA had requested information on stent interaction on multiple occasions, e.g. pre-IDE meeting 10/20/03; disapproval letter 3/18/04; disapproval letter 6/16/04*". (App. 47)(emphasis added).

On September 29, 2004, the company announced to its Medical Advisory Board that it had tabled its efforts to gain approval of the device for human clinical trials in the U.S. (Charon depo., exh. 44, Medical Advisory Board Meeting Summary of September 29, 2004)("Mike Kallok presented the status of the in-stent restenosis trial. Attendees were notified that it was not going to be pursued and other indications were to be pursued.")

Borgersen's Job Performance was Good

After CSI terminated Borgersen's employment and before he pursued a claim against it, Dr. Shapland distributed the following memorandum to all employees:

"We are sorry to announce that Svenn will be leaving the Company as a full time employee at the end of the month to expand his consulting practice. The Company will continue to utilize his skills on a consulting basis as specific needs or projects arise. We wish Sven (sic) the very best in the future and *thank him for his numerous contributions* in developing the Company to this stage."

(App. 42)(emphasis added). This memorandum is inconsistent with any definition of "cause" for discharge under the Agreement.

CSI also presented Dr. Borgersen with a consulting contract at the time of his termination. (Kallok depo., exh. 37). The proposed agreement required him to “provide his expertise and knowledge to CSI from time to time as agreed upon by Consultant and CSI, which information shall be used by CSI in engineering and testing advice and analysis of the OAS”. Id. The offer of a consulting contract is inconsistent with the definition of “cause” under the original employment agreement. Dr. Kallok admitted that had Dr. Borgersen done anything to willfully or intentionally harm the company, CSI would never have offered him the consulting contract. (Kallok depo., 106-07).

III.

ARGUMENT

A. The Standard of Review

On appeal from summary judgment, the appellate court examines the lower court's decision for two things: (1) whether there are genuine issues of material fact in dispute, and (2) whether the lower court erred in its application of the law. *Sigurdson v. Carl Bolander & Sons, Co.*, 532 N.W.2d 225, 228 (Minn. 1995). When examining facts, the reviewing court must take them in the light most favorable to the nonmoving party. *Iacona v. Schrupp*, 521 N.W.2d 70, 72 (Minn.App. 1994). The court must resolve all doubts and factual inferences against the moving party. The reviewing court owes no deference to the lower court's application of the law and reviews the court's conclusions *de novo*. The burden of persuading the right to summary judgment always rests upon the moving party. *Polk v. Mut. Serv. Life Ins. Co.*, 344 N.W. 2d 427, 429 (Minn. App. 1984).

Summary judgment has been described as a "blunt instrument." *Lindner v. Lund*, 352 N.W.2d 68, 70 (Minn. App. 1984). The court must therefore exercise due caution to ensure a trial where bona fide disputes exist as to material facts. *Couillard v. Charles T. Miller Hospital, Inc.*, 253 Minn. 418, 92 N.W.2d 96 (1958). Whether the court believes the nonmoving party will prevail or not at trial is irrelevant on summary judgment. *Writers, Inc. v. West Bend Mutual Ins. Co.*, 465 N.W.2d 419, 422 (Minn. App. 1991); *Whisler v. Findeisen*, 280 Minn. 454, 456, 160 N.W. 2d 153, 155 (1968). In passing on a motion for

summary judgment, the function of the court is solely to determine whether any fact issues exist, not to decide issues of fact. *Nord v. Herreid*, 305 N.W. 2d 337, 339 (Minn. 1981). It is not a substitute for trial. *Whisler*, 160 N.W.2d at 155.

Conflicting explanations on material issues of fact are not matters for summary judgment. *State v. Allina Health System*, 679 N.W. 2d 400, 406-07 (Minn. App. 2004) Similarly, credibility issues are not summary judgment material. *Longrie v. Luthen*, 662 N.W.2d 150, 154-55 (Minn. App. 2003). Summary judgment is appropriate only if the moving party has established the right to judgment with such clarity as to leave no room for doubt. *Drager by Gutzman v. Aluminum Industries Corp.*, 495 N.W.2d 879 (Minn. App. 1993), rev. denied (Minn. April 20, 1993).

B. The District Court Erred as a Matter of Law in Considering Extrinsic Evidence in the Interpretation of an Express Employment Contract When the Contract Was Not Ambiguous and Contained an Integration Clause

The well-oiled rule in employment law is that “[a]bsent an express contract the usual employer-employee relationship is terminable at will by either party.” *Harvet v. Unity Medical Center, Inc.*, 428 N.W. 2d 574, 577 (Minn. App. 1988) citing *Cederstrand v. Lutheran Brotherhood*, 263 Minn. 520, 532, 117 N.W.2d 213, 221 (1962)(emphasis added). Either side is free to leave the employment of the other, with or without cause, at any time for any reason.

The operative language in the rule, however, is “absent an express contract”. *Id.* The parties in this case had exactly that: an express contract that required cause for discharge.

(App. 36). This Court recently confirmed that “an employment agreement may supersede the at-will doctrine if it contains either termination conditions or a specified duration.” *Kvidera v. Rotation Engineering and Manufacturing Co.*, 705 N.W. 2d 416, 421 (Minn. App. 2005).

The District Court nonetheless held Dr. Borgersen to be an at-will employee of CSI. In reaching this conclusion, the Court relied upon a cover letter sent with the contract and disregarded the language of the contract itself. (Conclusion of Law No. 7). This conclusion is an error of law. The Agreement is unambiguous in its requirement of cause for discharge. The Court should never have looked beyond the language of the Agreement itself.

“Contract interpretation is a question of law, which [the Court of Appeals] reviews *de novo*. *Kvidera*, 705 N.W. 2d at 420. ““The language found in a contract is to be given its plain and ordinary meaning.” *Id.*, citing *Turner v. Alpha Phi Sorority House*, 276 N.W. 2d 63, 67 (Minn. 1979).

The Agreement was Fully Integrated

The parties had signed a fully integrated contract which by its terms did not allow for the consideration of any extrinsic evidence. The Agreement contains the following integration clause:

“11.1 Integration. This agreement embodies the entire agreement and understanding among the parties relative to subject matter hereof and supersedes all prior agreements and understandings relating to such subject matter.”

(App. 40). The language “[t]his agreement embodies the entire agreement and understanding among the parties relative to the subject matter hereof” is clear and decisive on the issue. The integration clause in this case must, as a matter of law, foreclose all consideration of extrinsic evidence. “The very object of the parties in reducing the contract to writing is that it shall no longer be subject to dispute.” *Thiem v. Eckert*, 165 Minn. 379, 383 (1925).

In *Alpha Real Estate v. Delta Dental Plan, Minn.*, 664 N.W. 2d 303 (Minn. 2003), the Minnesota Supreme Court rejected the use of extrinsic evidence where there has been a written contract containing an integration or merger clause like the one present here. *Alpha Real Estate*, 664 N.W. 2d at 313. The Court noted the clause and said “[t]his merger clause specifically states that it is the ‘entire agreement between the parties’ . . . Thus, under these facts, we need not look beyond the writing of the 1997 lease itself to determine whether it is a complete integration.” *Id.* (emphasis added). The Court then refused to consider any evidence of any other alleged agreements or terms that purported to alter the written agreement.

Furthering this conclusion is paragraph 1 of the Agreement:

“1. Nature and Capacity of Employment. The Corporation hereby agrees to employ Employee as Director of Design and Analysis, *pursuant to the terms of this Agreement.*”

(App. 36)(emphasis added). Paragraph 1 does not say “pursuant to the terms of this Agreement except as to discharge for cause, in which case we meant the terms of a cover letter.”

“Pursuant to the terms of th[e] Agreement”, the Court must then look to paragraph

2 of the Agreement:

“2. Term of Employment. The term of this Agreement shall commence on a mutually agreed-to date, but no later than January 13, 2003 and continue until terminated by either party as *provided for hereunder*.”

(App. 36)(emphasis added).

The “as provided for hereunder” referenced in paragraph 2 comes in paragraph 7, which sets forth only four circumstances under which the Agreement can be terminated by CSI. The first requires cause, the last three allow for termination in the event of death, disability or dissolution of the corporation. The “with cause” provision is as follows:

“7. Termination of Employment.

“7.1 With Cause. Notwithstanding anything contained herein to the contrary, the Corporation, acting by and through its Board of Directors, shall have the right to immediately terminate Employee’s employment under this Agreement for ‘Cause,’ which shall mean: (I) the willful and continued failure by the Employee to substantially perform Employee’s duties with the Corporation; or (ii) the willful engaging by Employee in conduct which is demonstrably and materially in the opinion of the Board injurious to the corporation, monetarily or otherwise.

(App. 37).

Finally, paragraph 11.6 of the Agreement states as follows:

“11.6 Modifications. This Agreement shall not be modified or amended except by a written instrument signed by the parties.”

(App. 40) As in *Alpha Real Estate* above, this clause further supports the finding that the contract itself is all that can be looked to as a matter of law.

The District Court nonetheless decided that the cover letter and the Agreement must be read together. (Conclusions of Law 6-10). The Court based its entire reasoning on its conclusion that “the ‘cause’ portion of the Employment Agreement does not state that it is the exclusive means by which Borgersen’s employment could be terminated.” (Conclusion of Law 10). This Conclusion is erroneous. While paragraph 7 does not expressly state that it is the exclusive means of termination, paragraph 2 does: “[t]he term of this Agreement shall . . . continue until terminated by either party as *provided for hereunder*.” It also ignores paragraph 1 of the Agreement, which unambiguously states that “[t]he Corporation hereby agrees to employ Employee . . . *pursuant to the terms of this Agreement*.” Finally, the integration clause in paragraph 11.1 plainly makes the Agreement the only operative document. There is nothing in the Agreement itself which incorporates the terms of any cover letter or states that employment is at will.

The District Court’s Reliance on Farrell v. Johnson

The Court relied upon *Farrell v. Johnson*, 442 N.W. 2d 805, (Minn. App. 1989) in support of its conclusion that the two documents need to be read together. *Farrell* holds that “[g]enerally, instruments *executed at the same time*, by the same parties, relating to the same transaction will be considered and construed together, since they are, in the eyes of the law,

one contract or instrument.” *Farrell*, 442 N.W. 2d at 806-07 (emphasis added); (Conclusion of Law No. 6).

The Court has erred in its application of *Farrell* to this case. The cover letter was only executed by Kallok, not by Borgersen. It is simply a cover letter enclosing an integrated contract. More importantly, in *Farrell* the parties had a merger or integration clause in one of their documents. The clause was held inapplicable, however, because it was contained *in the first document* signed between the parties. The Court found that the merger clause did not bar “consideration of a *subsequent* written document” like the one sought to be enforced. *Farrell*, 442 N.W. 2d at 806 (emphasis added). Of significance to Borgersen is the Court’s observation that “[a] merger clause *is usually conclusive* in determining whether the agreement is completely integrated for purposes of the parol evidence rule.” *Id.* (emphasis added). *Farrell* is plainly an exception to the general rule that an integration/merger clause will bar consideration of other alleged agreements.

The Criteria for Enforcement of Alleged Collateral Agreements

The cover letter does not meet the criteria established by the Minnesota Supreme Court for the enforcement of alleged collateral agreements.

“The Minnesota Supreme Court has stated that in construing the surrounding circumstances of a writing which appears on its face to be fully integrated, three conditions must exist:

‘(1) the agreement must in form be a collateral one; (2) it must not contradict express or implied provisions of the written contract; (3) it must be one that parties would not ordinarily be expected to embody in the writing . . . [o]r, again, it must not be so clearly connected with the principal transaction as to be part and parcel of it.’”

Apple Valley Red-E-Mix v. Mills-Winfield, 436 N.W. 2d 121, 124 (Minn. App. 1989), quoting *Taylor v. More*, 195 Minn. 448, 453, 263 N.W. 537, 539 (1935). Here, the cover letter contradicts the provisions of the written contract contained in paragraphs 1, 2, 7, and 11.1. This case involves two diametrically opposing interpretations of contract language in two separate documents concerning how the contract can be terminated. There are mutually exclusive terms in the cover letter and the Agreement that cannot be reconciled. The statement in the cover letter that “[t]his letter and the enclosed Employment Agreement summarize our understanding of the terms of your employment” cannot be fairly reconciled with paragraphs 1, 2 and 11.1 of the Agreement, all of which purport to make the Agreement itself the exclusive and final word on the terms of the employment relationship and how it can be terminated.

Further, a contract cannot be both terminable at-will and for cause. They are by definition mutually exclusive. *Cederstrand*, 117 N.W. 2d at 221. (“Unless plaintiff can establish that she was to be dismissed only for cause by proving a contract to that effect, her employment could be terminated at any time and without cause.”) If the contract is

terminable at-will, then the “for cause” language is meaningless. “At-will”, by definition means “with or without cause”. If the contract is terminable only for cause, then the at-will language is meaningless. The cover letter cannot be harmonized with the Agreement without gutting the essence of much of the Agreement itself.

An at-will provision is also the type of term that the parties would “ordinarily be expected to embody in the writing”, particularly if the Agreement has a clause that states the circumstances under which employment can be terminated. At-will employment goes to the very heart of the nature of the employment relationship. Since the cover letter does not meet the criteria set forth above for enforcement of alleged collateral agreements, the Court must as a matter of law deny effect to the cover letter.

Paragraphs 1, 2, 7 and 11.1 Are Meaningless if the Cover Letter Governs

The Minnesota Supreme Court has said that “[a] contract must be interpreted in a way that gives all of its provisions meaning.” *Current Tech. Concepts, Inc. v. Irie Enterprises*, 530 N.W. 2d 539, 541 (Minn. 1995). “Because of the presumption that the parties intended the language used to have effect, we will attempt to avoid an interpretation of the contract that would render a provision meaningless.” *Chergosky v. Crosstown Bell, Inc.*, 463 N.W. 2d 522, 526 (Minn. 1990).

Following the District Court’s holding would render the entire termination section of the contract meaningless. Spelling out in great detail the four circumstances under which the employer can terminate the contract and stating in paragraph 2 that the Agreement can only

be terminated “as provided hereunder” are all meaningless if this was just intended to be an at-will agreement.

Ambiguities Are Construed In Dr. Borgersen’s Favor

The “well-established rule of contract construction [is] that when a contract is open to two conflicting interpretations, the one more favorable *to the party who did not draft the instrument* should be adopted in the absence of a clear showing that a contrary meaning was intended by the parties at the time of its execution.” *ICC Leasing Corp. v. Midwestern Mach. Co.*, 257 N.W. 2d 551, 555 (Minn. 1977). The responsibility for making clear the intention of the parties rests as a matter of law with the drafter of the instrument. If it had the opportunity to make its intention more clear but did not do so, it does not get the benefit of the doubt from the court. *Wisconsin Town Lot Co. v. Astleford*, 301 Minn. 331, 334, 222 N.W.2d 285, 287 (1974). Here, had CSI wanted an at-will contract, it could easily have deleted the requirement of cause and stated in the Agreement that it was terminable at will. It did not do so. Appellant, who had no role in drafting the Agreement, should not suffer for it.

C. If the Court Looks Outside of the Contract for its Interpretation, the Intent of the Parties on the Issue of Termination of the Contract is a Genuine Issue of Material Fact in Dispute That Precluded Summary Judgment

Appellant contends that if the Court looks outside of the four corners of the Agreement to discern the intent of the parties as to whether the Agreement is terminable at-will or for cause, the matter of intent is for the jury to decide. The only way in which the

Court can look outside of the express contract language to discern intent is if the Court finds the language ambiguous. Construing ambiguous contract language is a question of fact for the jury. *Denelsbeck v. Wells Fargo & Co.*, 666 N.W. 2d 339, 346 (Minn. 2003). The jury would also be instructed that ambiguous contract language is construed against the drafter. *Hilligoss v. Cargill, Inc.*, 649 N.W. 2d 142, 148 (Minn. 2002).

If the Court permits extrinsic evidence on intent, the jury would also have to consider the veracity of Dr. Borgersen's contention that the at-will language in the cover letter meant nothing to him. The District Court made a finding of fact that Dr. Borgersen "testified he did not understand the cover letter and that it 'meant nothing' to him. Borgersen depo., p. 126. According to Borgersen, he and Kallok specifically discussed paragraph 7 because they both had a 'bad experience' at Boston Scientific. (citation omitted) Borgersen testified that 'we specifically discussed each clause and the fact that the only way that my position could be terminated was for cause as defined.'" (Finding of Fact 10). The Court appeared, however, to question the credibility of Dr. Borgersen's testimony when it recited his advanced education and employment history prior to reciting his testimony. *Id.*

If the Court was going to consider extrinsic evidence, a proposition appellant strenuously disagrees with, it should have considered all of the evidence. The cover letter by itself is not the only extrinsic evidence on the parties intent. Dr. Borgersen's testimony as to the parties' specific discussion of the termination issue must, as a matter of law, be credited on a motion for summary judgment, not discounted or ignored. The facts are

viewed in the light most favorable to the nonmoving party. *Iacona*, 521 N.W.2d at 72. Issues of credibility are for the factfinder. *Longrie v. Luthen*, 662 N.W.2d at 154-55.

D. The District Court Erred in Determining That Appellant Did Not Make a Report Protected by Minn. Stat. § 181.932

Minnesota's public policy discharge statute states that an employer shall not discharge an employee because "the employee . . . in good faith, reports a violation or suspected violation of any federal or state law or rule adopted pursuant to law to an employer or to any governmental body[.]" Minn. Stat. §181.932, subd. 1(a) (1988). An employee making a report under this law is commonly referred to as a "whistleblower".

The Minnesota Supreme Court has interpreted this statute to mean that "[a] whistleblower claim need not identify the specific law or rule that the employee suspects has been violated, so long as there is a federal or state law or rule adopted pursuant to law that is implicated by the employee's complaint, the employee reported the violation or suspected violation in good faith, and the employee alleges facts that, if proven, would constitute a violation of law or rule adopted pursuant to law." *Abraham v. Cty. of Hennepin*, 639 N.W. 2d 342, 354-55 (Minn. 2002).

The Minnesota Court of Appeals defined the term "report" in *Janklow v. Minnesota Bd. of Examiners for Nursing Home Administrators*, 536 N.W. 2d 20 (Minn. App. 1995), aff'd 552 N.W. 2d 711 (Minn. 1996). The Court noted that the whistleblower statute does not define "report" and "offers no basis to give the verb a meaning other than its dictionary

definition: '1. To make or present an often official, formal, or regular account of. 2. To relate or tell about; present.'" *Janklow*, 536 N.W. 2d at 23.

The Good Faith Reports

Dr. Borgersen reported to his superiors his good faith belief that certain test results had to be reported to the FDA because the device was not safe for human clinical trials. (App. 54). Gary Syring, the company's expert on FDA submissions, had earlier told Dr. Borgersen about what the FDA rules required for disclosing risks associated with the device. *Id.* Dr. Borgersen testified that he knew that in its initial application for IDE approval, CSI had "provided a risk analysis, but the risk analysis did not include this kind of an event and did not properly describe it or did not properly cover it." *Id.*

The District Court's Findings and Conclusions

The District Court held that Dr. Borgersen had not made a report protected by the whistleblower law. (Conclusion of Law 27). Its findings in support of this conclusion are replete with factual determinations resolved in favor of CSI. The District Court found "as a matter of law that at the time he talked to Shapland and Kallok, Plaintiff was only reporting a *bad test* to CSI. Whatever CSI put into its May 14, 2004, IDE report to the FDA, the IDE report was not prepared until after Plaintiff's 'report' to Shapland and Kallok. Plaintiff 'signed off' on one of the very documents integral to that submission, yet now comes forward claiming that CSI violated federal or state law or a rule adopted pursuant to law. Plaintiff's

conduct in signing off on the IDE report to the FDA is not consistent with his whistleblower claim.” (Conclusion of Law 25).

The Court was wrong in making a credibility determination on summary judgment. Conflicting explanations and credibility determinations rest with the factfinder. *Allina Health System*, 679 N.W. 2d at 406-07; *Longrie*, 662 N.W.2d at 154-55. The consistency or alleged inconsistency of Dr. Borgersen’s actions is a matter for the jury to weigh, not the Court. Dr. Borgersen testified that his signature went on a document that had been altered after he signed it and which contained test results that were different from what he signed off on. (App. 52-53). The weight to be given his signature is a matter for the jury.

The Court also found that “[n]o colorable basis exists to believe that, at the time Plaintiff made his alleged report, CSI *had* violated any federal/state statute or rule, because they had not. Fillopov’s test was not a ‘bench test’ but was an attempt to develop a bench test -- and it was those tests (the bench tests) that the FDA wanted done.” (Conclusion of Law 26).

Dr. Borgersen, however, disputed CSI’s contention that the test was not a valid bench test. (App. 51)(“[T]hey had a number of catastrophic failures during the testing process using test procedures *that were perfectly representative* of what was going on with the device to be used in the human body.”)(emphasis added). The photographing of the test results also negates CSI’s contention that it was not a valid test. The Court on summary judgment simply adopted the moving party’s view of the evidence, even though it was disputed.

The Timing of the Report

The District Court reasoned that “[n]o colorable basis exists to believe that, at the time Plaintiff made his alleged report, CSI *had* violated any federal/state statute or rule, because they had not.” (Conclusion of Law 26). When it comes to the timing of any whistleblower-type report, there are only two logical possibilities. Either the report comes before the violation of law or it comes after the law has been broken. If the report comes before the violation, then reporting serves the public purpose of hopefully preventing the violation. If it comes after the violation occurs, then it serves the public purpose of trying to correct the violation. Either purpose fits the designs of the legislature in enacting the whistleblower law. It would make no sense for the legislature to protect from job loss only the person who sought to correct the violation of law after it has happened and not the person who sought to prevent its occurrence.

Legislative Intent

The whistleblower law does not differentiate between a violation of law that has occurred or one that is about to occur. It simply speaks of “a violation or suspected violation of . . . law”. The Minnesota Supreme Court has suggested that there is no distinction to be made. *Hedglin v. City of Willmar*, 582 N.W. 2d 897, 902 (Minn. 1998) (“There may be fact questions as to whether any of these statutes were actually violated, but for purposes of the whistleblower statute, *it is irrelevant whether there were any actual violations*; the only

requirement is that the reports of state law violations were made in good faith.”)(emphasis added).

The statute clearly was intended to apply to both past and anticipated violations of law. In subdivision 1(c) of the law, the employee is protected from termination if he or she refuses an employer’s order to violate the law. Minn. Stat. § 181.932, subd. 1(c). Similarly in *Phipps v. Clark Oil & Refining Corp.*, 408 N.W. 2d 569 (Minn. 1987), the Minnesota Supreme Court approved the Court of Appeals recognition of a public policy exception to the at-will employment rule. The exception involved a service station attendant who refused a customer and employer’s requests to fill an unleaded car with leaded gasoline. The Clean Air Act, which prohibited the action, *had not been violated at the time* the employee refused the request. It would only have been violated had he fulfilled the request. Nonetheless, the employer’s termination of the attendant for refusing the request was held to be prohibited by public policy.

The Court in *Phipps* stated that “[t]he Clean Air Act is . . . a clearly mandated public policy to protect the lives of citizens and the environment[.]” *Phipps*, 408 N.W. 2d at 571. The same can easily be said of the FDA regulations. One goal of protecting employees from discharge for refusing to violate the law has to be the prevention of the violation of the law, whether it be the Clean Air Act or the FDA regulations.

The canons of statutory construction support this reading of the term “violation or suspected violation of . . . law” contained in Minn. Stat. § 181.932 subd. 1(a). “In

ascertaining the intention of the legislature the courts may be guided by the following presumptions: . . . (5) the legislature intends to favor the public interest as against any private interest.” Minn. Stat. § 645.17(5). While it may favor the private interest of employers to read the statute to apply to only past violations of law to narrow the scope of exposure, it clearly favors the public interest to read it as aiming to prevent future violations of law as well.

The legislature could have added modifiers such as “past” or “existing” to the phrase “violation or suspected violation”, but did not do so. Instead it left the phrase broad and undefined. “When the words of a law are not explicit, the intention of the legislature may be ascertained by considering, among other matters: (1) the occasion and necessity for the law; (2) the circumstances under which it was enacted; (3) the mischief to be remedied; (4) the object to be attained[.]” Minn. Stat. § 645.16.

On November 18, 1986, the Minnesota Court of Appeals handed down its version of *Phipps*, recognizing for the first time the public policy exception to the at-will employment rule. *Phipps v. Clark Oil & Refining Corp.*, 396 N.W. 2d 588 (Minn. App. 1986)(*hereinafter Phipps I*), *affirmed*, 408 N.W. 2d 569 (Minn. 1987)(*hereinafter Phipps II*). In 1987, the legislature did the same by enacting Minn. Stat. § 181.932. The Supreme Court in fact noted the passage of the law in its opinion reviewing the Court of Appeals decision. *Phipps*, 408 N.W. 2d at 571. The legislature broadened the holding of *Phipps I* in many ways, including outlawing termination for reports to an employer of violations or suspected violations of law.

The legislature's rapid endorsement of *Phipps I* in Minn. Stat. § 181.932, subd. 1(c) and its broadening of the holding to include other forms of whistleblower protection indicate its intent to go beyond *Phipps I* and give maximum protection to the employee who seeks to protect the public from harm, whether the report occurs before or after the violation.

The Past Violation of Law

Borgersen had a good faith belief the law had been violated by CSI prior to the time of his report. It is undisputed that it had submitted an application to the FDA for IDE approval on February 12, 2004. (Warner aff. exh. D, cover letter of February 12, 2004, to the FDA). CSI included animal testing on stent interaction, not the worst-case scenario bench testing that the FDA had requested in the pre-IDE meeting of October 20, 2003. (App. 43). In the pre-IDE meeting, the FDA "recommended that bench testing include an evaluation of the possible interaction between the OAD and stents *under worst-case conditions*. This testing was to demonstrate that there is no possibility of interaction between the OAD and stents, or that the worst-case interactions do not adversely affect the stents (i.e. fatigue life, stent structure, etc.)". *Id.* (emphasis added).

By not conducting the bench testing before submitting the IDE on February 12, 2004, CSI submitted an application that did not contain "information that is relevant to the safety and effectiveness of the device for the intended treatment use." 21 C.F.R. §812.36(c)(1)(vii). According to FDA regulations, an investigational plan is also supposed to be submitted which contains a "risk analysis." This risk analysis is to contain a "description and analysis

of all increased risks to which subjects will be exposed by the investigation [and] the manner in which these risks will be minimized.” 21 C.F.R. §812.25. The IDE application submitted on February 12, 2004, did not meet the standard of the regulations. Had CSI done what it was asked to do before it submitted its application, it would have had accurate bench testing results showing the true dangers of its device.

CSI may argue that it did not know of the risk at the time it submitted its application in February because the testing had not been conducted. The regulation, however, does not speak in terms of including only “known risks” in the application to the FDA. Such an interpretation would reward an applicant for doing minimal testing of its device. The FDA has a reasonable expectation that an applicant will have thoroughly tested a medical device before submitting an application asking the FDA to allow it to experiment with the device on people. CSI had not followed through and conducted the testing that the FDA had recommended in October. Because of this, in February it submitted a device for approval that did not contain a description of all “all increased risks”. By not having conducted the tests it should have conducted, CSI placed itself in violation of the FDA regulations.

After it finally did the testing in April, Dr. Borgersen then told Dr. Shapland and Dr. Kallok that they needed to report the results to the FDA. He was trying to get CSI to correct the risk analysis that had been submitted earlier to the FDA. (App. 54) He knew the risk analysis was inaccurate and therefore in violation of FDA regulations. *Id.* The FDA later faulted CSI for not reporting the testing. (App. 47). “No investigation or documentation of

the initial entanglement was performed until 8/04 and *it was not reported to FDA though FDA had requested information on stent interaction on multiple occasions, e.g. pre-IDE meeting 10/20/03; disapproval letter 3/18/04; disapproval letter 6/16/04*").

The Effort to Prevent Further Violation of Law

Dr. Borgersen's reports also had the salutary mission of trying to prevent a further misrepresentation to the FDA in CSI's response to the FDA's questions. It is against FDA regulations to misrepresent a product to the FDA by the omission of information on increased risks associated with the product. 21 C.F.R. § 812.30(b)(2). As of May 14, 2004, CSI had no argument that it did not know of the increased risks.

Dr. Borgersen did what the legislature would have wanted him to do. He in good faith tried to protect the public from harm by getting his employer to comply with FDA regulations. Both seeking to correct the improper assessment of risk in the application of February 12, 2004, and seeking to prevent the illegal omissions in the submission of May 14, 2004, were protected by the whistleblower law. The legislature intended to protect him from job loss for reporting in good faith the suspected violations of federal regulations.

IV.

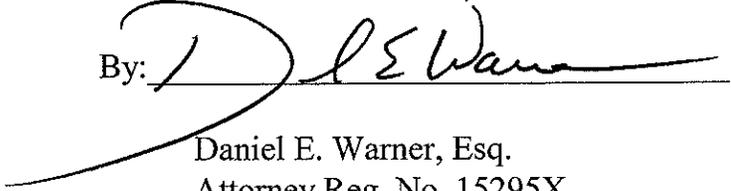
CONCLUSION

Based upon the foregoing, Appellant respectfully asks the Court of Appeals to reverse the grant of summary judgment and remand the case for trial.

Dated: May 24, 2006.

Respectfully submitted,

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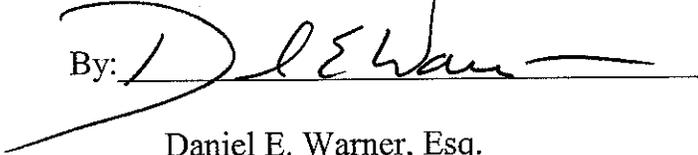
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CERTIFICATION

I certify that this brief conforms to Rule 132.01 of the Minnesota Rules of Appellate Procedure for a brief using proportional font of 13 point or larger. The length of this brief is 9,697 words. This brief was prepared using WordPerfect 12.0.

Dated: May 24, 2006.

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The appendix to this brief is not available for online viewing as specified in the *Minnesota Rules of Public Access to the Records of the Judicial Branch*, Rule 8, Subd. 2(e)(2) (with amendments effective July 1, 2007).